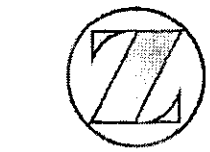
K110836 (pg. 1 of 3)



OCT - 7 2011

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

510(k) Summary

Sponsor:	Zimmer, Inc. SulzerAllee 8 CH-8404 Winterthur, Switzerland
Contact Person:	Daniel J. Williman Specialist, Regulatory Affairs Telephone: 574-371-8065 Fax: (574) 372-4605
Date:	September 28, 2011
Trade Name:	*CLS*® *Brevius*™ Stem with *Kinectiv*® Technology
Product Code / Device:	LZO - Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented LPH - Prosthesis, hip, semi-constrained, metal/polymer, porous uncemented KWA - Prosthesis, hip, semi-constrained (metal uncemented acetabular component) JDL - prosthesis, hip, semi-constrained (metal cemented acetabular component) LWJ - Prosthesis, hip, semi-constrained, metal/polymer, uncemented KWZ - prosthesis, hip, constrained, cemented or uncemented, metal/polymer JDI – prosthesis, hip, semi-constrained, metal/polymer, cemented
Regulation Number / Description:	21 CFR 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

21 CFR 888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

21 CFR § 888.3330 - Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

21 CFR 888.3320 - Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis

21 CFR 888.3360 - Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis

21 CFR § 888.3310 – Hip joint metal/polymer constrained, cemented or uncemented prosthesis

21 CFR § 888.3350 – Hip joint metal polymer, semi-constrained cemented prosthesis

Predicate Device:

CLS™ *Spotorno*™ Femoral Stem, manufactured by Zimmer Austin, Inc., K042249, cleared September 15, 2004

Zimmer® M/L Taper Hip Prosthesis with *Kinectiv*™ Technology System, manufactured by Zimmer Inc., K081007, cleared May 6, 2008

Zimmer® M/L Taper Hip Prosthesis with *Kinectiv*™ Technology System, manufactured by Zimmer Inc., K071856, cleared July 30, 2007

Zimmer® M/L Taper Hip Prosthesis with Modular Neck Technology, manufactured by Zimmer Inc. K063251, cleared January 24, 2007

Device Description:

The *CLS Brevius* Stem with *Kinectiv* Technology is a modular, titanium alloy femoral stem designed to replace the proximal femur in total or hemi-hip arthroplasty. It is a wedge-shaped, collarless design with a proximal-to-distal taper and a trapezoidal cross-section. The proximal portion of the stem contains a tapered female junction to allow for attachment to *Kinectiv* Technology modular necks and features for attachment of insertion/extraction

	instrumentation.
Intended Use:	Total hip replacement for patients with: • Noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis. • Femoral neck fractures. • Failed previous surgery where pain, deformity, or dysfunction persists. • Revision of previously failed hip arthroplasty. Hemi-hip replacement for patients with: • Femoral neck fractures. This femoral stem is for cementless use only.
Comparison to Predicate Device:	The *CLS Brevius* system is similar or identical in intended use, materials, sterility, and performance characteristics to the predicate device(s).
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: The results of non-clinical (lab) performance testing demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices. Performance testing/analysis included: Proximal Stem Fatigue Test (including Finite Element Analysis to determine the worst case device for this test), Distal Stem Fatigue Evaluation, Primary Stability Test, Influence of Version Analysis, Accelerated Corrosion Fatigue Test, Distraction Test, and MR Evaluation. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zimmer, Inc.
% Mr. Daniel Williman
Associate Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

OCT - 7 2011

Re: K110836
Trade/Device Name: CLS® Brevius™ Stem with Kinectiv® Technology
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, JDL, LZO, LPH, LWJ, KWZ, JDI
Dated: September 28, 2011
Received: September 29, 2011

Dear Mr. Williman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110836

Indications for Use

510(k) Number (if known):

Device Name:

CLS® *Brevius*™ Stem with *Kinectiv*® Technology

Indications for Use:

Total hip replacement for patients with:

- Noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- Femoral neck fractures.
- Failed previous surgery where pain, deformity, or dysfunction persists.
- Revision of previously failed hip arthroplasty.

Hemi-hip replacement for patients with:

- Femoral neck fractures.

This femoral stem is for cementless use only.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110836